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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 01/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/845,724

Applicant(s)

CUI ET AL.

Examiner

David M. Naff

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 11 and 12 is/are pending in the application.
- 4a) Of the above claim(s) 4-8, 11 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8/22/01 . 6) ☐ Other: _____

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In a response of 10/27/03 to a restriction requirement of 9/26/03, applicants amended claims 4 and 7, canceled claims 9 and 10, added new claims 11 and 12, and elected Group I claims 1-3 with traverse. New claims 11 and 12 may go with Group III or IV since the
5 claims are dependent on claims 5, 6 or 8.

The traverse is on the ground that Groups I, II and IV should be examined together since claims 1-3 are drawn to a product, and should these claims be found allowable, the processes of Groups II and IV can be rejoined. However, being capable of rejoinder does not preclude
10 restriction, and the inventions of Groups I-IV are restrictable for reasons set forth in the requirement. In the event that claim 1 of Group I is found allowable, the claims of Groups II and IV may be rejoined, provided they contain all the limitations of allowable claim I and are free of rejection under 35 U.S.C. 112. The restriction
15 requirement is maintained, and made final with the exception that rejoinder of Groups II and IV with Group I may occur if claim 1 is found allowable.

Claims 4-8, 11 and 12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention,
20 there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the response of 10/27/03.

Claims examined on the merits are 1-3.

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C.

112:

5 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it
15 pertains, or with which it is most nearly connected, to make and/or use the invention.

20 The specification is unclear how the claimed microstructure level of agglomerated particles having a diameter of 5-50 microns as required in line 3 of claim 1, and the nanostructure level of multiple laminar structure having periodic repeated units, each periodic repeated unit having a thickness of 10-15 nm and consisting of a layer of nano-calcium phosphates and a layer of collagen as required in
25 lines 4-6 of claim 1 are produced. The description at page 2, lines 19-24, merely recites what is claimed, and does not describe how the microstructure level and the nanostructure level are obtained.

Example 1 describes precipitating calcium phosphate with collagen from a solution containing dissolved collagen, sodium phosphate and calcium

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chloride. It is unclear how this method results in the claimed microstructure level and nanostructure level.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C.

5 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10 Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The meaning and scope of "nano-calcium phosphates" in claim 1 and where recited in other claims is uncertain. Is this requiring calcium
15 phosphates particles of nano-size, or is something else being required?

Defining a microstructure level and nanostructure level in claim 1 is confusing as to whether both the microstructure level and nanostructure level are part of the composite, or are alternative
20 forms of the composite. If alternative forms, the different forms should be required in different claims. If both levels form the composite, the claim should be clear how both levels relate to each other in forming the composite.

Claim 1 is unclear as to material that forms the agglomerated
25 particles, and the relationship of the agglomerated particles to the composite. Do the particles that are agglomerated contain both nano-calcium phosphate and collagen, and if not, how do the particles form

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the composite? The structure required by "multiple laminar structure having periodic repeated units" is uncertain.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al (6,331,312 B1), and if necessary in view of Ying et al (6,013,591).

The claims are drawn to a nano-phosphate/collagen composite which in microstructure level is agglomerated particles of 5-50 microns, and in nanostructure level is a multiple laminar structure having periodic

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repeated units, each periodic repeated unit having a thickness of 10-15 nm and consisting of a layer of nano-calcium phosphates and a layer of collagen.

Lee et al describe bioresorbable ceramic composites, which can be
5 a composite of nano-size calcium phosphate (col 4, line 38) combined
with a matrix or additive (col 7, lines 41-43), which can be collagen
(col 9, line 37 and col 12, line 27) as a supplementary material (col
9, line 29 and col 12, line 15). The composite may be prepared by
mixing precursor materials of the calcium phosphate with the
10 supplementary material, and forming the calcium phosphate in the
presence of the supplementary material. In Example 1 (paragraph
bridging cols 18 and 19), the precursors, sodium phosphate and calcium
nitrate, are reacted to precipitate calcium phosphate.

Ying et al disclose producing nanocrystalline apatites (calcium
15 phosphate) for use as prosthetic implants. The small nano-size
provides advantages such as enhancing packing and densification to
enable pressureless sintering (col 5, lines 49-53).

When producing the composite of Lee et al, it would have been
obvious to use collagen as the supplementary material, and form the
20 composite by adding the precursors of the calcium phosphate to a
solution of collagen and precipitating the calcium phosphate with
collagen as suggested at col 13, lines 45-51. This procedure would
have resulted in a composite as presently claimed. The collagen of
Lee et al is type I as required by claim 2. The ratio of calcium
25 phosphate to collagen in claim 3 encompasses the ratio in bone, and

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would have been obvious. If needed, Ying et al would have further suggested nano-calcium phosphate.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff
5 whose telephone number is 703-308-0520. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this
10 application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

15



David M. Naff
Primary Examiner
Art Unit 1651

20 DMN
1/9/04